IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	)	Group Art Unit: 1631
McDONOUGH *et al.*	)	Examiner: Marschel, A.
Serial No. 08/480,472	)	Atty. Docket No. GP034-03.DV1
Filed: June 6, 1995	)	**VIA FACSIMILE**
For: NUCLEIC ACID SEQUENCE AMPLIFICATION	)	

DECLARATION UNDER 37 C.F.R. § 1.131

Box AF
Commissioner for Patents
Washington, D.C. 20231

Sir:

We, Sherrol H. McDonough, Daniel L. Kacian, Nanibhushan Dattagupta, Diane L. McAllister, Philip W. Hammond, Thomas B. Ryder and Yeasing Y. Yang, co-inventors of the above-identified patent application, upon information and belief hereby declare as follows:

1. Prior to May 6, 1992, we conceived of and reduced to practice in the United States compositions comprising first and second oligonucleotides having a primer sequence and a 5' promoter sequence, where one of the oligonucleotides included a modification at or near the 3' end of the primer sequence for reducing or blocking extension of the primer sequence. The compositions further comprised a target nucleic acid sequence, a third oligonucleotide having a primer sequence but no promoter sequence, an RNA-dependent DNA polymerase and an RNA polymerase that recognized the promoter sequence of the first and second oligonucleotides. Evidence of this prior conception and reduction to practice was recorded in a laboratory notebook belonging to Yeasing Yang. Copies of the relevant laboratory notebook pages are attached hereto as Exhibit A. While the dates on these laboratory notebook pages have been redacted, the activities set forth therein were performed in the United States prior to May 6, 1992.

2. The laboratory notebook pages of Exhibit A evidence a transcription-based amplification procedure performed by Yeasing Yang using distinct T7 promoter-primers identified as "T7AMtbA-246" and "T7AMtbA-246-cordycepin." *See* Book No. 2211 at page 46. The nucleotide sequences of these promoter-primers were identical but the promoter-primers differed in that the T7AMtbA-246 promoter-primer was unmodified (*i.e.*, unblocked promoter-primer) while the T7AMtbA-246-cordycepin promoter-primer included cordycepin at its 3' end (*i.e.*, blocked promoter-primer). The amplification mixture of the test samples contained 0.1 pmol unblocked promoter-primer and 15 pmol blocked promoter-primer. Also included in the amplification mixture of the test samples were 2 pmol primer, identified as "MgoA+146," 5 fg rRNA from *Mycobacterium tuberculosis*, reverse transcriptase ("RT") and T7 RNA polymerase ("T7"). The controls were identical to the test samples, as indicated in section "I" on page 46 of Book No. 2211, except that the controls contained no *Mycobacterium tuberculosis* rRNA.

3. Results from the amplifications are set forth at page 47 of Book No. 2211 in Exhibit A and are indicated in relative light units (RLU). The controls in these results correspond to numbers 29 and 30 and provide background RLU values. Based on these background values, it is clear that the targeted rRNA was amplified in samples containing the unblocked promoter-primer, the blocked promoter-primer having cordycepin at its 3' end, and a primer. Test samples containing both blocked and unblocked promoter-primers correspond to numbers 15-19 in the results.

We hereby declare that all statements made herein of our own knowledge are true, and that statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of this application and any patent issuing therefrom.

DECLARATION

Serial No. 08/480,472
Atty. Docket No. GP034-03.DV1

Date: 3-28-02 By: Sherrol H. McDonough
Sherrol H. McDonough

Date: 4-1-02 By: Daniel L. Kacian
Daniel L. Kacian

Date: _____ By: _____
Nanibhushan Dattagupta

Date: _____ By: _____
Diane L. McAllister

Date: _____ By: _____
Philip W. Hammond

Date: _____ By: _____
Thomas B. Ryder

Date: _____ By: _____
Yeasing Y. Yang

DECLARATION

Serial No. 08/480,472
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Date: _____ By: _____
Sherrol H. McDonough

Date: _____ By: _____
Daniel L. Kacian

Date: March 26, 2002 By: Nanibhushan Dattagupta
Nanibhushan Dattagupta

Date: _____ By: _____
Diane L. McAllister

Date: _____ By: _____
Philip W. Hammond

Date: _____ By: _____
Thomas B. Ryder

Date: _____ By: _____
Yeasing Y. Yang

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Serial No. 08/480,472
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Date: _____ By: _____
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Date: 3-26-02 By: Diane L McAllister
Diane L. McAllister

Date: _____ By: _____
Philip W. Hammond

Date: _____ By: _____
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Date: _____ By: _____
Yeasing Y. Yang

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Date: _____ By: _____
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Nanibhushan Dattagupta

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Date: 3/28/02 By: _____
Philip W. Hammond

Date: _____ By: _____
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Date: _____ By: _____
Yeasing Y. Yang

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Daniel L. Kacian

Date: _____ By: _____
Nanibhushan Dattagupta

Date: _____ By: _____
Diane L. McAllister

Date: _____ By: _____
Philip W. Hammond

Date: Mar 27, 2002 By: _____
Thomas B. Ryder

Date: _____ By: _____
Yeasing Y. Yang

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Atty. Docket No. GP034-03.DV1

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Date: _____ By: _____
Nanibhushan Dattagupta

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Date: _____ By: _____
Philip W. Hammond

Date: _____ By: _____
Thomas B. Ryder

Date: March 24, 2002 By: Yeasing Yang
Yeasing Y. Yang